Biotech Daily

Monday August 21, 2017

Daily news on ASX-listed biotechnology companies

*** ASX, BIOTECH DOWN: DIMERIX UP 11%, ITL DOWN 7%**

*** MONASH BIOMEDICINE DISCOVERY INSTITUTE JOINS MRCF**

*** ITL REVENUE UP 12% TO $35m, PROFIT UP 897% TO $3.4m**

*** TEVA LAUNCHES GENERIC OF ACRUX, LILLY AXIRON**

*** BOTANIX READY FOR PHASE Ib BTX1503 ACNE TRIAL**

*** RESAPP RECEIVES $516k FEDERAL R&D TAX INCENTIVE**

*** IMPEDIMED SUBMITS FDA SOZO HEART FAILURE APPLICATION**

*** MEDIBIO STARTS FDA-DIRECTED CARDIAC RHYTHM DEPRESSION TRIAL**

*** NUHEARA WELCOMES US OTC HEARING AID ACT**

*** RESONANCE BEGINS TESTING ARTIFICIAL INTELLIGENCE IRON TEST**

*** CELLMID CLAIMS 98% ÉVOLIS HAIR GROWTH SUCCESS**

*** OPTISCAN REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** NOXOPHARM REQUESTS 'CAPITAL RAISING' TRADING HALT**

*** ANATARA, ZOETIS NEGOTIATE DETACH FOR ANIMAL DIARRHOEA**

*** NEUROTECH TAKES PROMOSALUTE ITALIAN DEAL TO 50% CASH UP-FRONT**

*** FMR TAKES 5% OF RESMED, ADDS TO BIOTECH INVESTMENTS**

*** THORNEY TAKES 6% OF MICRO-X**

*** PRIMA APPOINTS GRANT CHAMBERLAIN DIRECTOR**

*** BIONOMICS, MERCK SHARP DOHME NEUROSCIENCE SYMPOSIUM**

MARKET REPORT

The Australian stock market fell 0.37 percent on Monday August 21, 2017 with the ASX200 down 21.2 points to 5,725.9 points. Twelve of the Biotech Daily Top 40 stocks were up, 24 fell, two traded unchanged and two were untraded. All three Big Caps fell.

Dimerix was the best, up 0.1 cents or 11.1 percent to one cent with 116,666 shares traded. Admedus climbed 6.5 percent; Genetic Signatures was up 5.1 percent; both Cellmid and Living Cell improved 4.2 percent; both Actinogen and Prana were up 3.8 percent; Clinuvel and Reva rose more than two percent; with Acrux, Starpharma and Viralytics up by less than one percent.

ITL led the falls, down 3.5 cents or 7.4 percent to 44 cents with 364,972 shares traded. Airxpanders, LBT, Mesoblast and Orthocell lost more than six percent; both Atcor and Neuren were down 5.7 percent; Prima fell 4.55 percent; Benitec and Impedimed were down more than three percent; Avita, Nanosonics, Osprey, Universal Biosensors and Uscom shed more than two percent; with Bionomics, Cochlear, CSL, Ellex, Factor Therapeutics, Oncosil, Opthea, Pharmaxis and Pro Medicus down less than one percent.

MEDICAL RESEARCH COMMERCIALISATION FUND

The Medical Research Commercialisation Fund says that Melbourne's Monash Biomedicine Discovery Institute has joined the Fund.

The Fund said that the collaboration with Melbourne's Monash Biomedicine Discovery Institute would enable early-stage medical research opportunities from the Institute BDI to be funded and developed locally, providing flow-on benefits to the Australasian biotechnology ecosystem and the wider economy, creating local jobs, national prosperity and ultimately global healthcare outcomes.

The Brandon Capital-managed MRCF said the Monash Biomedicine Discovery Institute was launched at Monash University in November 2016 (BD: Nov 14, 2016).

The MRCF said that the Institute had more than 120 research teams, made up of 700 researchers from across multiple health disciplines, working towards six global health priorities: cancer, cardiovascular disease, human development and stem cells, infection and immunity, metabolic disease and obesity, and neuroscience.

Monash Institute director Prof John Carroll said the MRCF collaboration was a strategic relationship that further validated the Institute's basic research fundamentals, and capacity for industry engagement.

"This collaboration aligns with and complements the institute's strategic goals around the translation of research and will provide a direct link to a dedicated source of early-stage capital, sophisticated investors and the extensive commercial, clinical and research network that the MRCF offers," Prof Carroll said.

The MRCF said it had $530 million under management.

MRCF chief executive officer Dr Chris Nave said his Fund had been "aware of the world-class medical research capabilities at Monash University for some time".

"The recent formation of the Monash [Biomedicine Discovery Institute] provided an ideal opportunity for us to align our mutual interests in biomedical research translation," Dr Nave said.

ITL

ITL says revenue for the 12 months to June 30, 2017 was up 11.9 percent to $34,774,000 with net profit after tax up 896.8 percent to $3,429,000.

ITL executive chairman Bill Mobbs said that revenue was up 12 percent "through development of new customers and markets and by continued introduction of new and innovative products".

Mr Mobbs said that ITL continued to invest and spent more than $4 million on research and development for new products, development of the Myhealthtest business and in sales and marketing activities to expand current markets and diversify into new markets.

Mr Mobbs said that profits had increased as the company benefitted from investments in patented, innovative products, with manufacturing efficiencies driven by further investment in the manufacturing facility in Malaysia and from reductions in raw material costs from strategic sourcing and business improvement projects.

Mr Mobbs said the "trend will continue as the group takes advantage of new products due to be released during the next 12 months and from expansion of its customer base".

ITL said that it had cash and cash equivalents of $2,690,000 at June 30, 2017 compared to $611,000 at June 30, 2016, diluted earnings per share was up 821.05 percent to 3.50 cents compared to the previous year's 0.38 cents, with net tangible asset backing per share up 26.4 percent from 9.1 cents to 11.5 cents.

ITL said there would be no dividend this year.

ITL fell 3.5 cents or 7.4 percent to 44 cents.

ACRUX

Acrux says Teva Pharmaceutical has launched a generic version of its Axiron testosterone replacement therapy in the US.

Acrux said that it and partner Eli Lilly and Co believed that the Axiron axilla application patent was valid and enforceable and the companies were “committed to asserting their intellectual property rights for Axiron and the appeal and proceedings remain underway, with the hearing expected to be heard by the end of 2017.

Last year, Acrux said the US District Court for the Southern District of Indiana ruled the granted formulation and axilla application patents had been invalidated and would not be infringed by the commercialization of generic versions of Axiron by the generic companies that challenged the patents (BD: Aug 23, 2016).

Acrux said at that time that with Eli Lilly it was “disappointed with the US District Court’s ruling” and the next day lodged an appeal (BD: Aug 24, 2016).

The company said that with Eli Lilly it had filed lawsuits against Perrigo Israel Pharmaceuticals, Watson Laboratories, known as Actavis, Amneal Pharmaceuticals and Lupin Pharmaceuticals, each of which had filed an abbreviated new drug application for a generic version of Axiron, for infringement of certain issued US patents.

Today Acrux said that the applicator patent was held valid but not infringed by the majority of parties and during the pendency of the appeal, the formulation patent expired and was no longer subject to the appeal proceedings.

Acrux was up half a cent or 1.9 percent to 27 cents.

BOTANIX

Botanix says it ethics approval for a 20-patient, phase Ib study of its topical cannabidiol BTX1503 solution for acne.

In July Botanix said its 20-patient phase Ia study showed “excellent safety and tolerability of BTX1503” with little to no skin irritation and no severe adverse events used as a single dose either once or twice on day-1 followed by a washout period, then starting on day-8, either once or twice daily for 14 days (BD: Jul 3, 2017).

Today, Botanix said it expected to complete the study by the end of December 2017.

The company said that each patient would receive BTX1503 treatment over a 4-week period with safety assessments, including local skin tolerability to BTX1503 performed throughout the four weeks, and patients would be monitored for treatment effects on lesion counts and for improvements in their acne.

Botanix executive director Matt Callahan said the trial would be “primarily focused on acne patient safety, [but would] also collect data concerning improvements in acne signs and symptoms”.

“Data that demonstrates a reduction of acne lesions and an overall improvement in skin condition will support the potential for BTX1503 as one of the first new clinical products to treat acne in more than 20 years,” Mr Callahan said.

Botanix fell 0.2 cents or 3.85 percent to five cents with 17.3 million shares traded.

RESAPP HEALTH

Resapp says it has received $516,305 from the Australian Tax Office under the Federal Government Research and Development Tax Incentive program.

Resapp said the rebate related to research and development expenditure for the year to June 30, 2016

Resapp fell 0.1 cents or 1.5 percent to 6.7 cents with 10.5 million shares traded.

IMPEDIMED

Impedimed says it has submitted its 510(k) application to the US Food and Drug Administration for Sozo for patients living with heart failure.

Impedimed said the submission was for a bio-impedance spectroscopy-connected platform for use in hospitals, clinics and in patient's homes under a clinician's direction.

The company said that Sozo was intended to monitor patients who lived with heart failure, took diuretic medication, lived with fluid management problems, lived with end-stage renal disease, were recovering from coronary artery disease related event, or suffered from recurrent dehydration.

Impedimed chief executive officer Richard Carreon said the company was "extremely pleased that we have been able to move so quickly on filing the next 510(k) submission for Sozo to the FDA".

"A critical requirement in obtaining our clearance is data, showing that values obtained from Sozo, are substantially equivalent to our own predicate device," Mr Carreon said.

Impedimed fell two cents or 3.1 percent to 62.5 cents.

MEDIBIO

Medibio says it has begun its 200-patient depression diagnostic confirmatory study for a 510(k) submission to the US Food and Drug Administration by July 2018.

Medibio said the preceding exploratory study of its cardiac rhythm diagnostic "demonstrated excellent performance … with overall accuracy of 82 percent, specificity of 84 percent and sensitivity of 78 percent".

The company said the cohort would be split evenly between individuals with major depressive disorder and non-depressed controls.

Medibio chief executive officer Jack Cosentino said the study would "play a key role in securing FDA clearance of the world's first device-based diagnostic for depression" and the company had a pipeline of diagnostic and monitoring products for post-traumatic stress disorder, anxiety, bipolar disorder, and other mental illnesses.

Medibio fell 0.5 cents or 1.4 percent to 36 cents.

NUHEARA

Nuheara has welcomed an Act signed by US President Donald Trump to "fundamentally change the way millions of Americans can access affordable hearing devices".

Nuhear said that the Over-the-Counter Hearing Aid Act of 2017 would make certain types of hearing aids more accessible to people with mild to moderate hearing loss, without the need to be seen by a certified and licenced audiologist or hearing instrument dispenser.

The company said that the Bill required the US Food and Drug Administration to regulate the new category of over the counter hearing aids to ensure they meet the same high standard of safety, consumer labelling and manufacturing protection that all other medical devices must meet.

Nuheara said its business model was built around delivering multi-functional and affordable hearing technology products to the global market and its Iqbuds sound filtering ear buds provided assistive audio by using hearing technology to enhance the consumer's ability to hear in the world around them.

Nuheara chief executive officer Justin Miller said "it's not often that a new piece of legislation in the US helps draw attention to, and subsequently firm up, such a potentially huge market opportunity".

Nuheara was up 0.2 cents or 2.6 percent to 7.8 cents with 14.9 million shares traded.

RESONANCE HEALTH

Resonance says it will begin beta-testing its artificial intelligence product for rapid, low-cost liver-iron-concentration analysis by the end of September 2017.
Resonance said that testing the internet “cloud” based product the used its Ferriscan protocol was “an important milestone” as part of its strategy to increase market share in emerging growth markets.
The company said the beta-testing would evaluate the user-interface and usability of the new product alongside Ferriscan over a 30-day period and then it would be refined and evaluated across multiple centres.
In June, Resonance said that the Nicosia, Cyprus-based Thalassaemia International Federation supported its low cost liver iron concentration diagnostic and its machine-learned artificial intelligence prototype for a low-cost test followed a study that showed a need for an affordable product to measure liver iron concentration in developing nations, where a widely-available but unvalidated magnetic resonance imaging transverse relaxation time technique known as T2* was potentially endangering patients’ lives (BD: Jun 14, 21, 2017).
Today, Resonance said that Ferriscan was the only US Food and Drug Administration cleared method for the magnetic resonance imaging assessment of liver-iron-concentration.
Resonance was up 0.2 cents or 9.1 percent to 2.4 cents with 1.6 million shares traded

CELLMID

Cellmid says that 78 of 79 subjects (98%) in a 120-day trial of its Évolis hair growth products recorded new growth with 77 reporting reduced hair loss.
Cellmid said that in addition to efficacy 76 participants felt their hair texture was improved and 69 users improved at least one grade on the Hamilton Norwood or Ludwig hair loss scales, the international hair loss scales for men and women.
The company said that the consumer study results were critical for its US retail strategy and the data would be the key resource for the underlying marketing and public relations activities that drove brand awareness and sales.
Cellmid said that participants used the full range of Évolis products including shampoo, conditioner and activator over 120 days, with monthly reviews conducted by trained hair assessors.
The company said that the results were recorded and users were photographed with a high-resolution camera in a controlled setting from several angles to document their progress.
Cellmid said that users with persistent dandruff also reported improvement in their condition over the test period.
The company said that the study was designed to collect efficacy data on hair loss and hair growth, assess the change in hair quality, colour safety and multiple user parameters such as feel, smell, lathering, conditioning and volumizing ability.
Cellmid was up 0.1 cents or 4.2 percent to 2.5 cents with 2.5 million shares traded

OPTISCAN

Optiscan has requested a trading halt “pending an announcement … to the market in relation to a proposed capital raising”.
Trading will resume on August 23, 2017 or on an earlier announcement.
Optiscan last traded at 9.3 cents.

NOXOPHARM

Noxopharm has requested a trading halt “pending the release of an ASX announcement regarding a proposed capital raising”.
Trading will resume on August 23, 2017 or on an earlier announcement.
Noxopharm last traded at 43 cents.

ANATARA LIFESCIENCES

Anatara says Zoetis has exercised its option to negotiate an agreement to develop, distribute and market its Detach non-antibiotic diarrhoea treatment (BD: Jan 30, 2017).
Anatara said that the Florham Park, New Jersey-based Zoetis licence negotiations followed a research evaluation and licence option period with Zoetis completing a preliminary evaluation of the pineapple-stem derived bromelain-based Detach as a non-antibiotic approach to help control scours, or diarrhoea in certain livestock.
The company said the negotiations could take “some months to complete and there is no guarantee that a transaction will be completed”.
In January, Anatara announced its second undisclosed milestone payment from Zoetis, later filing an Appendix 4C quarterly report for the three months to March 31, 2017 citing $328,000 in “other commercial income” (BD: Jan 30, 2017)
Last year, an Appendix 4C quarterly report for the three months to June 30, 2016 cited $2,283,000 in “receipts from customers” (BD: Jul 22, 2016).
Today,Anatara executive chairman Dr Mel Bridges said the company was “delighted to now be moving into formal negotiations for Detach’s development and commercialization”.
Last year, Anatara said it would develop Detach for human use and appointed former Alchemia chief scientific officer Dr Tracey Brown as chief development officer to oversee the human trials of Detach for gastro-intestinal disease including irritable bowel syndrome, inflammatory bowel disease and travellers’ diarrhoea (BD: Nov 22, 2016).
Anatara was up 28 cents or 29.5 percent to $1.23.

NEUROTECH INTERNATIONAL

The Malta-based Neurotech says it has restructured its agreement with Italian distributor Service and Technology S.A.T Ltd also known as Promosalute.
Neurotech said that Promosalute had not met its obligations to take Mente Autism, with delivery and payment outstanding for 90 units.
The company said that it had agreed with Promosalute to vary the distribution agreement from October 2017 and the new agreement would require the remaining 90 units to be delivered by December 31, 2017, with each order initiated on receipt of a 50 percent upfront payment from Promosalute.
The company said that the agreement required Promosalute to place minimum orders and complete payment for Mente Autism units over an initial contract term to mid-2019, with the potential for an extension.
Last year, Neurotech said the shipment of 30 Mente Autism devices to Italy was a “major milestone” and its Italian distribution agreement would see the purchase of a minimum of 8,700 units over three years (BD: Dec 22, 2016).
Today, Neurotech said that Promosalute continued to monitor the process for inclusion of neurofeedback therapy within the Italian Ministry of Health’s guidelines on the treatment and management of autism which “would facilitate reimbursement for the cost of Mente Autism devices under the government’s social assistance system”.
Neurotech fell 0.1 cents or 8.6 percent to 16 cents.

RESMED

Fidelity Management & Research (FMR) says it has become a substantial shareholder in Resmed with 7,123,933 shares or 5.01 percent.
The Boston, Massachusetts-based FMR previously said it was a related party to Fidelity International Limited (FIL) with investments in Acrux, Cochlear, CSL and Heartware.
FIL previously said it was substantial in Acrux, Clinuvel, Cogstate, Factor Therapeutics, Impedimed, Medibio, Resapp, Somnomed and Starpharma.
According to Fidelity Investments website it was established as the international investment arm of FMR becoming independent in 1980, and was "owned mainly by management and members of the original founding [Johnson] family".
Today, FMR said it acquired shares between April 18 and August 16, 2017 in more than 1,200 trades ranging from one US share to 821,162 US shares at prices from $US67.46 to $US78.91, equivalent to $A9.18 to $A10.38 per Australian share, respectively.
Resmed fell eight cents or 0.9 percent to $9.24 with 1.9 million shares traded.

MICRO-X

Thorney Technologies says it became a substantial shareholder in Micro-X with 8,856,760 shares (6.14%) on April 10, 2017.
The Melbourne-based Thorney said it acquired 2,500 shares for 44 cents a share on April 10 and 805,160 shares for 40 cents a share on May 9, 2017.
Thorney did not state the cost of its previous acquisitions.
The company said that the shares were held by Thorney Technologies, Thorney Investment Group and Tiga Trading Pty Ltd.
Micro-X was unchanged at 41 cents.

PRIMA BIOMED

Prima says it has appointed Grant Chamberlain as a non-executive director effective immediately.
Prima said that Mr Chamberlain was formerly Bank of America Merrill Lynch Australia's head of mergers and acquisitions and had more than 20 years' experience in investment banking including positions at Deutsche Bank and Nomura.
Prima fell 0.1 cents or 4.55 percent to 2.1 cents with 3.7 million shares traded

BIONOMICS

Bionomics says it will co-host with Merck Sharpe and Dohme a one-day Adelaide neuroscience symposium in October, in conjunction with the 2017 Ausbiotech conference.
Bionomics said the program, entitled 'The Frontiers of Neuroscience: Feelings and Forgetting' would focus on the importance of finding suitable treatment options for cognitive conditions, and would be opened chief executive officer Dr Deborah Rathjen and closed by Merck Sharp and Dome's head of business development and licencing Ben Thorner, with presentations from Kings College London's Prof Steve Williams, Harvard Medical School's Prof Ole Isaacson and Celgene's Dr Richard Hargreaves.
Bionomics said registration was free and for more information email Dr Lauren Nicotra at: symposium@bionomics.com.au.
Bionomics fell half a cent or 1.1 percent to 44 cents.